

Amendment and Response

Applicant: Kenneth M. Adams et al.

Serial No.: 10/657,915

Filed: September 9, 2003

Docket No.: M190.145.101 / P-263.00 US

Title: SURGICAL MICRO-BURRING INSTRUMENT AND METHOD OF PERFORMING SINUS SURGERY**REMARKS**

This is responsive to the Non-Final Office Action mailed August 8, 2007. In that Office Action, claim 30 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 1, 9, 17, 22, and 23 were rejected under 35 U.S.C. §102(b) as being anticipated by Adams, U.S. Patent No. 6,503,263 ("Adams '263"). In the alternative, claims 1, 9, 17, 22, and 23, as well as claims 2-8, 10-14, and 30-32, were rejected under 35 U.S.C. §103(a) as being unpatentable over Adams '263 in view of Marino et al., U.S. Patent No. 6,280,447 ("Marino"). Claims 15, 16, and 34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Adams '263 and Marino, and further in view of Toriumi et al., U.S. Patent No. 6,214,009 ("Toriumi"). Claims 18 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Adams '263 and Marino, and further in view of Adams, U.S. Patent No. 6,312,438 ("Adams '438"). Claims 20 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Adams '263 and Marino in view of Adams '438. Claim 24 was rejected under 35 U.S.C. §103(a) as being unpatentable over Adams '263 and Marino and further in view of West, Jr., U.S. Patent No. 5,364,395 ("West").

With this Response, claims 1, 2, 9, 10, 13, 17, and 33 have been amended; claims 14 and 30 have been canceled; and claims 35 and 36 have been added. Claims 1-13, 15-24, and 31-36 remain pending in the application and are presented for reconsideration and allowance.

35 U.S.C. §112, First Paragraph, Rejection

With this Response, claim 30 has been canceled. Thus, the rejection under §112, first paragraph, is moot.

35 U.S.C. §§102, 103 Rejections

As an initial point of clarification, the Office Action references Adams '263 as being prior art under §102(b). Adams '263 issued January 7, 2003. The pending application was filed September 9, 2003. Because Adams '263 in and of itself was not patented more than one year prior to the filing date of the pending application, Adams '263 does not qualify as prior art under

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§102(b). Applicant acknowledges the existence of U.S. Publication No. 2002/0038130 (publication of the application later resulting in Adams '263), and presents the following arguments based upon its possible availability as prior art.

Claim 1 has been amended to recite features of the pocket that render the micro-burring instrument highly amenable for use with the claimed bur. In particular, amended claim 1 recites that the pocket is defined by a side wall having an upper edge including a proximal zone, an intermediate zone, and a distal zone. Relative to an orientation in which a bottom surface of the pocket is the lowest-most surface thereof, the proximal zone extends downwardly from a proximal portion of the outer tubular member. The intermediate zone extends from the proximal zone at an angle differing from that defined by extension of the proximal zone. Finally, the distal zone extends downwardly from the intermediate zone at a differing angle, terminating at a distal-most end of the pocket. One non-limiting example of the construction is provided in FIG. 3A. With this structural arrangement, the pocket exposes a significant circumferential surface of the bur for interacting with tissue. These differing zones/extensions set forth in amended claim 1 are markedly different from the uniform window wall 39 resulting in the relatively small windows 38, 62 illustrated in FIGS. 3B and 4B, respectively, of Adams '263. In fact, the relatively small cutting window associated with Adams '263 renders the design inappropriate for bur-type applications.

Notably, the above distinctions represent more than just an "obvious matter of design choice to one skilled in the art" as otherwise asserted in the Office Action in rejecting, for example, claims 10, 13, 14, and 33 as being obvious over Adams '263 in view of Marino. Clearly, Adams '263 does not teach the zones/extension features of amended claim 1. In fact, because Adams '263 does not envision use of a bur, one of skill would have no reason to depart from the singular, angular cutting window wall extension wall reflected in FIGS. 3B and 4B. Notably, Marino, otherwise relied upon in the Office Action as teaching a bur useful with the Adams '263 device, is similarly limited. In particular, the bur 16 of Marino provides cutting teeth 32 only at an interior surface thereof as shown in FIG. 6. With this construction, operation of the Marino tissue resector entails complete proximal retraction of the bur 16 from the window

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15, followed by insertion of a facet joint 18 within the window 15. Subsequently, the bur 16 is distally advanced to internally resect the facet joint 18. As best shown in FIGS. 2 and 9, then, the wall edge 17 has a downwardly extending proximal segment, a linear intermediate segment, and an upwardly extending distal segment. Marino requires this construction to provide a closed end 13 that prevents the distal end 21 of the bur 16 from contacting tissue. *Marino at col. 2, l. 56 – col. 3, l. 3*. Thus, one of skill upon reviewing Marino would, at best, understand to modify the cutting window 38 of Adams ‘263 such that a distal region/zone of the window’s edge extends upwardly, in direct contrast to the features of amended claim 1.

Notably, in advancing a position that the claimed shapes/configurations are of a type that a person of ordinary skill would find obvious for the purpose of providing a pocket region, it is respectfully submitted that the Office Action is improperly applying an “obvious-to-try” rationale in support of the obviousness rejection. In particular, an obviousness rejection cannot be based upon a theory that one of skill would have thought to vary all parameters or try each of numerous possible choices until possibly arriving at a successful result in instances where the prior art gives no indication of which parameters are critical or no direction as to which of many possible choices is likely to be successful. Thus, because Adams ‘263 gives no direction as to which of many possible choices is likely to be successful in generating a pocket configuration appropriate for use with a bur, the features of claim 1 are non-obvious over Adams ‘263. *MPEP §2145.X.B*. In fact, the only bur-related reference cited in the Office Action (Marino) teaches away from the features of claim 1. For at least these reasons, then, it is respectfully submitted that claim 1 is allowable over the cited art.

Claims 2-13, 15-24, and 31-34 depend from claim 1 and thus, for at least the above reasons, are allowable. In addition, it is respectfully submitted that at least claim 33 recites additionally distinct subject matter. Claim 33 provides that the distal-most end of the pocket is below a central axis of the lumen of the outer tubular member. FIGS. 3B and 4B of Adams ‘263 clearly do not teach this feature. Further, Marino teaches an entirely closed pocket configuration, thus leading one of skill away from the features of claim 33. Pointedly, the

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configuration of claim 33 facilitates desired exposure of the bur, a structural characteristic not envisioned by Adams '263, and in direct opposition to the bur device of Marino.

Newly Presented Claims

Newly presented claim 35 depends from claim 19 and thus, for at least the above reasons, is allowable. In addition, claim 35 recites that the upper edge of the pocket is shaped such that when the bur is distally-most positioned, the axial opening provided by the bur is unobstructed by the outer tubular member. Support for this language is found, for example, in FIG. 6. With this construction, then, irrigation fluid is readily passed through and exteriorly expelled from the bur, with the flow thereof being unobstructed by the walls otherwise defining the pocket. In contrast, the micro-resecting instrument of Adams '263 provides a radially-open cutting implement (i.e., the cutting tip 150 is radially open), such that axial flow of fluid is of no concern. As a result, Adams '263 does not teach the pocket configuration of claim 35. Marino is even further removed, teaching a circumferentially closed distal pocket end. Thus, claim 35 recites additionally allowable subject matter.

Newly presented claim 36 depends from claim 1 and is thus allowable. In addition, claim 36 recites that the bur is configured to remove hard bone with rotation of the inner tubular member. In contrast, the micro-shaving or resecting instrument of Adams '263, and in particular the cutting tip 150, is not a bur and thus is not capable of removing hard bone. The inventors of the present application specifically averred to this drawback of Adams '263 (*Application at pg. 2, ll. 14-24*). Thus, claim 36 further defines over at least Adams '263.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-13, 15-24, and 31-36 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-13, 15-24, and 31-36 are respectfully requested.

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No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

Dicke, Billig & Czaja, PLLC

Attn: MD Matters

Fifth Street Towers, Suite 2250

100 South Fifth Street

Minneapolis, MN 55402

Customer No. 63496

Respectfully submitted,

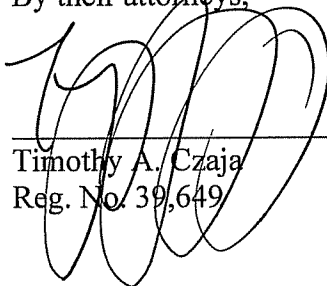
Kenneth M. Adams et al.,

By their attorneys,

Date:

TAC:jms

October 8, 2007



Timothy A. Czaja
Reg. No. 39,649